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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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01/16/2001

Ichiro Azuma

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2292 7590 06/25/2008  
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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

06/25/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/743,750	AZUMA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	VANESSA L. FORD	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 26-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application<br>6) <input type="checkbox"/> Other: _____. |
|---|--|

**FINAL ACTION**

1. This action is response to Applicant's amendment and remarks filed March 12, 2008. Claims 26 and 27 have been amended. Claims 1-25 have been canceled. Claims 26-29 are under examination.

***Rejections Withdrawn***

2. In view of Applicant's amendment and response the following rejections have been withdrawn:

- a) rejection of claims 21-23 under 35 U.S.C. 102(b), pages 2-3, paragraph 2.
- b) rejection of claims 21-26 under 35 U.S.C. 102(b), pages 4-5, paragraph 3.
- c) rejection of claims 21-26 under 35 U.S.C. 102(b), pages 5-6, paragraph 4.
- d) rejection of claims 21-26 under 35 U.S.C. 112 second paragraph, page 7, paragraph 5.
- e) rejection of claims 21-26 under 35 U.S.C. 112 second paragraph, page 8, paragraph 6.
- f) rejection of claim 24 under 35 U.S.C. 112 second paragraph, page 8, paragraph 7.
- g) rejection of claims 27-29 under 35 U.S.C. 112 second paragraph, page 9, paragraph 8.
- h) rejection of claims 27-29 under 35 U.S.C. 112 second paragraph, page 9, paragraph 9.

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- i) rejection of claims 27-29 under 35 U.S.C.103(a), pages 10-13, paragraph 10.

***New Grounds of Rejection Necessitated by Applicant's Amendment  
New Matter***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 3. Claims 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.* The amendment filed March 26, 2008 introduces new matter into the claims.

35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant's amendment introduces "new matter" that is not supported by the original disclosure. The specification fails to disclose the recited claim limitations" wherein the emulsion is dispersed without any particles that have a diameter of 100 µm or more..." . The Examiner has reviewed the instant specification and cannot not find support for this newly submitted claim limitation. Applicant is required to cancel the new matter in the reply to this Office Action.

***Written Description***

4. Claims 26-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Written Description Training Materials, March 25, 2008. See Example 1 in particular.

The instant claims, independent claim 27 in particular, is drawn to an oil-in-water emulsion comprising a bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil wherein the emulsion is dispersed without any particles that have a diameter of 100  $\mu\text{m}$  or more, is negative for agglutination reaction with lectin, and is obtained by the following steps:

(a) stirring a mixture of Bacillus Calmette-Guerin cell wall skeleton, an oil and an organic solvent to disperse the Bacillus Calmette-Guerin cell wall skeleton in the mixture;

(b) evaporating off the organic solvent to form an oil droplet wherein the Bacillus Calmette-Guerin cell wall skeleton is homogeneously dispersed, or an oil droplet wherein the Bacillus Calmette-Guerin cell wall skeleton is encapsulated in the oil; and then,

(c) adding an aqueous solution containing a surfactant thereto, and emulsifying the mixture.

The claimed oil-in-water emulsions do not meet the written description provision of 35 USC 112, first paragraph. The specification teaches that the average particle diameter is in the range of 0.1 to 20  $\mu\text{m}$ , preferably 1 to 10  $\mu\text{m}$  and more preferably 1 to 5  $\mu\text{m}$ . See page 15 of the instant specification. The specification teach that crude particles that are visible have usually a diameter of about 100  $\mu\text{m}$  or more. See page 18 of the specification. Claim 15 filed on January 16, 2001, discloses the claim limitation "...wherein the oil droplet is dispersed in a manner that the diameter of the particle is about 100  $\mu\text{m}$  or less".

There is no disclosure of an oil-in-water emulsion comprising a *Bacillus Calmette-Guerin* (BGC) cell wall skeleton encapsulated in an oil wherein the emulsion is dispersed *without any particles that have a diameter of 100  $\mu\text{m}$  or more* in the instant specification. No information is provided in the specification from which a person of ordinary skill in the art could predict that the oil-in-water emulsions of the invention would be *without any particles that have a diameter of 100  $\mu\text{m}$  or more*.

The state of the art regarding oil-in-water emulsions is cited below. Zbar et al (*Journal of National Cancer Institute*, 1972, Vol. 48, No.3, p. 831-835) teach compositions comprising BCG cell walls and mineral droplets (see the Abstract and pages 831-832). Zbar et al teach that the oil droplets of the prior art ranged from less than 1  $\mu$  to greater than 15  $\mu$ . The cited art has taught that oil-in-water emulsions have droplets of a ranged from less than 1  $\mu$  to greater than 15  $\mu$ . Since the disclosure has failed to reduce to practice any oil-in-water emulsions comprising a *Bacillus Calmette-Guerin* cell wall skeleton encapsulated in an oil wherein the emulsion is dispersed *without any*

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*particles that have a diameter of 100  $\mu\text{m}$  or more*, those of skill in the art would not consider the Applicant to be in possession of the claimed genus of oil-in-water emulsions.

Therefore, the specification fails to satisfy the written description requirement of 35 U.S.C. 112 first paragraph with respect to the full scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. . Claim 27 recites "...wherein the emulsion is dispersed without any particles that have a diameter of 100  $\mu\text{m}$  or more...". The newly amended claim limitation is indefinite because it does not recite an upper limit. Additionally, it is unclear as to what the term "particle" refers to. Does the term particles refer to the cell wall skeleton or oil particles within the oil-in-water emulsion? Clarification/correction is required.

#### ***Status of Claims***

6. No claims allowed.

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7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/  
Patent Examiner, Art Unit 1645  
June 16, 2008

/N. M. Minnifield/  
Primary Examiner, Art Unit 1645